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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,872	04/15/1998	DAVID A. ESTELL	GC527	1073

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
060872	ESTELL et al
Examiner	**Group Art Unit**
SAUNDERS	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 5/4/01 & 9/21/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 14, 17-28 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☑ Claim(s) 20-22 is/are allowed.

☑ Claim(s) 14, 17-19, 23-28 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 24

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

The amendment of 9/21/01 has been entered. Claims 14 and 17-28 are pending and under examination.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, lines 1, 3 and 5 "the protein" lacks antecedent basis:

Claims 14, 18-19 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Base claim 18 contains new matter.

Specifically, the only disclosure of adherent monocyte-derived dendritic cells was provided in Example 1 (page 26, lines 1-8). It is to be noted that in Example 1 these dendritic cells were obtained from the same naive individual as that from whom the naive T-cells were obtained. See page 26, lines 19-20. See also page 9, lines 28-30 and original claim 12, part (a) teaching that the dendritic cells and naive T-cells are obtained from a single blood source.

Since claim 18 does not require that the adherent monocyte derive dendritic cell of part (a) (I) and the naive T-cell of part (a) (ii) be from the same naive individual (i.e. a single blood source), applicant's claimed method encompasses embodiments, with respect to the source of the dendritic cell, which were not originally contemplated by applicant.

Claims 14 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant did not possess the genus of sequences from homologs (human or non-human) which can be substituted as recited in parts (a) and (b) of claims 14 and 23.

Applicant's disclosure has not adequately described what are sequences from the protein/protease of interest that are sequences which produce an altered or lesser allergenic response.

Applicant has not identified what are such homologs in terms of structure which would differentiate them from homologous which produce an allergenic response. The sequences of homologs which might produce a lessened allergenic response would include a large and diverse group of structural variants. There is no disclosure of the distinguishing attributes (even highly homologous sequences could still induce T-cell responses if they retain a motif which is recognized by MHC and T-cell receptors) of the genus. Structural features that would distinguish the sequences of the genus from other homologous sequences have not been disclosed. Mere statements of a desired goal or a disclosure of how one might find such do not constitute a description of the genus of desired homologs per se.

The prior art rejections of record have been withdrawn.

The examiner concurs that Garman et al. do not teach the use of naive T-cells.

The examiner likewise concurs that the T-cells of Bhardwaj et al. were from sensitized (non-naive) individuals.

The examiner notes that the dendritic cells of Mackay et al. are cell lines derived from the bone marrow of a p53 growth suppressor gene deficient animal. As such the cell lines would not be obtained from the same single source of human blood as the, naive T-cells, as required by instant claims 17 and 20, part (a) of each.

The examiner also notes that Mackay et al. do not teach obtaining the dendritic cells from blood (col. 5, lines 10+). As such the dendritic cells of Mackay et al. would not be "adherent monocyte derived" as required by claim 18, part (a) (I). Note Herbert et al. for teaching that monocytes are from blood.

New prior art rejections are stated as follows.

Claims 14, 17-18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garman et al. (5,820,862) in view of Macatonia et al., Mehta-Damani et al. or Takamizawa et al.

Garman et al. have been previously cited (papers 8, 15 and 20) for teaching identification of T-cell epitopes within a protein allergen and modification thereof (via substitution of amino acid residues) to provide peptides which induce a lowered or not any proliferative response of T-cells as applicant has correctly stated in the response of Papers 18 and 29, Garman et al. fail to teach the use of naive T-cells. Rather they teach epitope screening with T-cells from sensitized individuals.

Each of the secondary references (all cited on From 1449) teaches that one can obtain human blood samples and derive dendritic cells (DCs) and naive T-cells therefrom such that the DCs can present antigen to the naive T-cells to induce a proliferative response.

It would have been obvious that one would identify epitopes within the allergen of Garman et al. by using DCs and naive T-cells from a blood sample as taught by the secondary references. Motivation to do so would have been to conduct tests using blood cells from non-sensitized individual so that one would not need to find patients with the allergic disorder.

Applicant's urgings regarding these references have been noted (See Paper 25). Applicant basically relies upon the teachings of Schlienger et al. (Post dating reference). The examiner does not see how this reference points away from the claimed invention, nor does the examiner note where Schlienger et al. teach that DCs cannot stimulate naive T-cells. Applicant's comments are directed to how the authors of the three cited references prepared their Dcs and the maturity of the Dcs obtained. In response, the examiner notes that the instant claims state nothing about the stage of maturity of the Dcs. Thus even if Macatonia et al. used mature Dcs, this does not detract from their teachings. The examiner finds applicant's comments regarding Mehta-Damani et al. unconvincing. Applicant admits dendritic cells could present antigen, while macrophages could not. The instant claims require use of dendritic cells, not macrophages. Thus Mehta-Damani et al. point to the instant invention.

Applicant's urgings that Takamizawa et al. deplete PBMC of adherent cells are unconvincing with respect to instant claim 17, which states nothing about adherence or non-

adherence of the Dcs obtained from the blood. Furthermore, the examiner notes that page 2135, 1st col. teaches "Monocytes were then depleted by adsorption with human IgG coated petri dishes." This step occurs after a step in which Dcs had been permitted to differentiate from a CD2+ cell depleted population, which is not the population that stimulates naive T-cells. See abstract. Thus this reference remains applicable to claim 17.

Applicant's urgings filed on 5/4/01 have been considered but are unconvincing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 a.m. to 4:45 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

Dec. 17, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644